HIRTZ

Operating Instructions

Hyperthermia unit

HICO-AQUATHERM 660

CE 0124

HICO

seit 1945

HIRTZ & Co. KG
Bonner Str. 180
D-50968 Cologne

Phone: +49 (0)2 21 / 37 67 8 – 0
Fax: +49 (0)2 21 / 37 67 8 – 85

eMail: hirtz@hico.de
Internet: www.hico.de

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1 General

Please read the information in this manual to become acquainted with the HICO-AQUATHERM 660 as quickly as possible to be able to utilize its functions to the full extent.

1.1 Information regarding these instructions

These operating instructions are part of the HICO-AQUATHERM 660 (hereafter referred to as unit) and contains important notes concerning commissioning, safety, intended use as well as care and maintenance of the unit.

All illustrations and drawings in these operating instructions serve the purpose of general understanding and are not relevant with respect to design details.

These operating instructions must be available at all times, preferably near the unit. They must be read by any person involved in the:

- commissioning,
- operation,
- cleaning,
- Maintenance,
- Trouble shooting

of the unit.

1.2 Warnings

The following warning notes are used in these operating instructions:

⚠DANGER

A warning note of this danger level identifies an imminent dangerous situation.

Not avoiding this dangerous situation will cause severe injury or even death.

► Follow the instructions given in this warning note to avoid the danger of death or severe injury to persons.

⚠WARNING

A warning note of this danger level identifies a possibly dangerous situation.

Not avoiding this dangerous situation can lead to severe injuries.

► Follow the instructions in this warning note to avoid the risk of injuries to persons.

⚠CAUTION

A warning note of this danger level identifies a possibly dangerous situation.

Not avoiding this dangerous situation can lead to minor or moderate injuries.

► Follow the instructions in this warning note to avoid the risk of injuries to persons.

CAUTION

A warning note of this danger level identifies the possibility of material damage.

Not avoiding this situation can lead to material damage.

► Follow the instructions in this warning note to avoid the risk of material damage.

NOTE

A note highlights additional information to assist in working with the unit.

1.3 Limitation of liability

All technical information, data and notes on installation, operation and care contained in this manual were up-to-date at the date of printing and have been entered to the best of our knowledge under due consideration of our previous experience and knowledge.
No claims can be enforced on the basis of information, illustrations and descriptions in these operating instructions.

The manufacturer accepts no responsibility for loss in the event of:

- failure to comply with the operating instructions
- unintended use
- unprofessional repairs
- technical modifications
- use of non-approved spare parts
- Unauthorized conversions and changes

Translations are made to the best of knowledge. We will not assume liability for translation mistakes, even if the translation was made by us or ordered by us. Only the original German text is binding.

1.4 Copyright

1.5 Manufacturer address

HIRTZ & Co. KG
Bonner Str. 180
D-50968 Cologne

Phone: +49 (0)2 21 / 3 76 78-0
Fax: +49 (0)2 21 / 3 76 78-85
E-mail: hirtz@hico.de

2 Safety

This chapter contains important safety notes for work with this unit.
This unit complies with the specified safety regulations. However, improper use can lead to personal injury or material damage.

2.1 Intended use

This unit is solely intended for the cooling or heating of water mats[1] used to warm a patient. Any other use exceeding the use described above is considered as unintended use.

⚠WARNING

Danger due to improper utilisation!

Dangers may arise from the unit if it is put to unintended use and/or if it is used for any other purposes.

- ► Only use the unit *for* the purpose is intended for.
- ► Follow the procedures *described* in these operating instructions.

Claims of any type because of damages resulting from unintended use are excluded.

The operating company is the sole bearer of the risk.

[1] In these operating instructions the term "water mat" describes all HIRTZ accessories, such as water mats, water blankets, -water collars, etc.

2.2 Personnel requirements

NOTE

- ► Work on/with the unit must only be carried out by persons who are authorized for this work because of their education and qualification. Apart from this these persons must also be entrusted with this work by the operator.
- ► Allow personnel to be trained, instructed, directed or undergoing general training to only work on or with the unit under the supervision of an experienced person.
- ► Persons who are under the influence of drugs, alcohol or medication that affects their responsiveness may under no circumstances carry out work on or with the unit.
- ► Dangers may arise from the unit if it is improperly used by untrained personnel.
- ► All generally valid legal and otherwise binding regulations for the avoidance of accidents and the protection of the environment as well as general health and safety requirements must be observed in addition to the operating instructions. The operator must instruct his personnel accordingly.

2.3 General Safety Advice

NOTE

For safe handling of the unit you should comply with the following general safety notes:

- ► Before start-up check the proper condition of the unit (mains cable, housing, couplings, etc.) and the water mats.
- ► Lay out hoses and water mats without creases and buckling.
- ► Do not touch hoses and water mats with pointed or sharp objects. The system is not able to work correctly with perforated mats.
- ► Fill the unit tank with distilled water[2], to which a germicidal agent[3] has been added.
- ► Operate the unit only after the tank has been closed with the screw cap.
- ► Stand the unit horizontally; inclination of the support area ≤ 3 %.
- ► Height difference between unit and water mat < 1 m.
- ► Do not cover the unit; there are ventilation slots on bottom and rear side.
- ► Observe the automatic function test when switching on.
- ► In continuous operation perform the automatic function test manually at least once every day.

[2] The use of tap water is also possible, depending on the water quality (e.g. water hardness) the lifetime of water contacting components in the unit will be reduced.

[3] approx. 10 % - 20 % SANOSIL (from Sanosil, Farchant)

- ► During operation check the water flow and the water level on the unit regularly.
- ► Operate the unit only with an appropriate water level.
- ► Strictly comply with the ambient temperature range (10 - 30 °C) and storage temperature range (10 - 40 °C).
- ► Apply appropriate measures to position the patient on or under the water mat (if necessary).
- ► Do not use water mats as electric insulation mats in combination with HF-surgery.
- ► Intermediate layers between patient and water mat (sheets, surgical cloths, gel-mats, etc.) adversely affect the heat transfer.
- ► Operate the unit only with HICO water mats and original accessories.
- ► Do not operate the unit in the presence of combustible gases.
- ► In hyperthermia mode do not use or combine the unit with other heat sources.
- ► Do not operate the unit in the vicinity of heat sources (spotlights, direct insolation, radiators/ radiant heaters, etc.).
- ► Perform maintenance and safety related inspections by following these operating instructions.

2.4 Danger sources

2.4.1 Danger of overheating

⚠WARNING

There is a risk that the patient may be overheated.

- ► Monitor the patient's temperature when using the unit and the water mat on the patient.

3 Transport and setup

3.1 Scope of delivery and transport inspection

The scope of delivery of the HICO-AQUATHERM 660 consists of:

- HICO-AQUATHERM 660 unit
- Power cable
- Hose bracket
- Operating Instructions
- Hose extension
- Water mats (optional, as ordered)

NOTE

► Check the delivery for completeness and visible damage.

► Immediately report an incomplete delivery or damage caused by inappropriate packaging or transport to the forwarding agent, the insurance company and the supplier.

3.2 Unpacking

To unpack the device:

- Take the unit out of its box and remove the packaging material.
- Stand the unit on a level and horizontal base with sufficient load bearing capacity.

3.3 Waste disposal of packaging material

The packaging material protects the unit against transport damage. The packaging material has been chosen under environmental and waste disposal related aspects and is therefore recyclable.

Returning packaging material to the material circulation system saves raw materials and reduces the amount of waste. Return packaging material, that is no longer needed, to the collecting locations for the recycling system »Grüner Punkt« (in Germany).

NOTE

► If possible keep the original packaging over the warranty period, to be able to pack the unit again properly in case of a warranty claim.

4 Commissioning

This chapter contains important information for commissioning the unit. Please follow these notes to avoid dangers and damages.

4.1 Safety Advice

⚠WARNING

Personal injuries and material damage may occur when commissioning the unit!

Please comply with the following safety notes to avoid dangers:

► The weight of the unit is approx. 9 kg. Transport, unpack and set up the unit with two persons.

4.2 Setting up

4.2.1 Requirements concerning the place of installation

For safe and fault-free operation of the unit the set up place

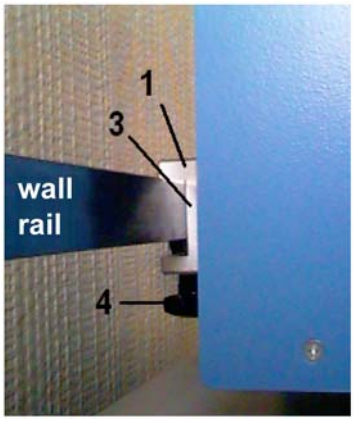
- must have sufficient load bearing capacity (weight of unit approx. 9 kg).
- must be level.
- must be horizontal (inclination ≤ 3 %).
- provide min. 20 cm clearance behind the back of the unit.
- must ensure sufficient ventilation of the device, e.g. in a rack trolley also upwards.
- must be at the same level as the water mat, i.e. with the bed of the patient (the unit may only be max. 1 m higher).

The optionally available five-castor stand (see under 4.2.3) meets these prerequisites.

NOTE

- ► If the unit is not horizontal, the display in the front of the unit will indicate the water level incorrectly.
- ► If the unit is far below the level of the water mat, the water circulation may be interrupted with heavy patients. Furthermore, water may flow back into the unit and cause overflowing of the water tank when the water filling socket is opened with the unit switched off.

4.2.2 Fixation on wall rail (optional)



The unit can also be fixed to the wall rails (5 x 20 mm), which are commonly used in hospitals. For this purpose fix the clamping holder (1), which is available as an accessory, preferably on the rear wall (or on the left side of the unit) with two screws (3) To do so

- loosen the optionally available clamping bracket (1) on the rear side of the unit, turn it to the required position and fix it again.

Use the star-handle screw (4) on the clamping bracket to fix the unit to the rail.

4.2.3 Setting up with five-castor stand (optional)

The five-castor stand, which is optionally available as an accessory, makes the stationary HICO-AQUATHERM 660 mobile.

Set up the unit together with the five-castor stand as follows:

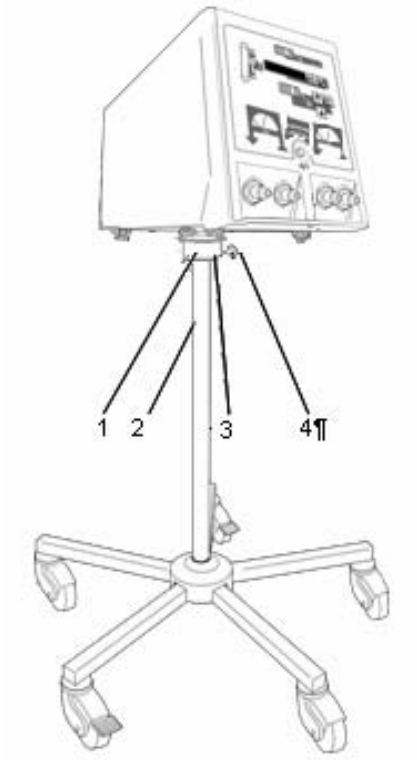
- Assemble the five-castor stand, as described in the assembly instructions.
- Fasten the clamping bracket (1), which is optionally available for the five-castor stand, with both screws (3) in the required position to the underside of the unit.
- Slide the HICO-AQUATHERM 660 over the vertical tube (2) of the five-castor stand.
- Fix the unit with the star knob screw (4).

⚠WARNING

Personal injuries and material damage may occur when commissioning the unit!

► To guarantee a safe function and for a stable fixed stay bar (2) it is necessary that during the assembly of the five foot rack:
- all 5 punches of the metallic disc lock into the wholes of the five foot extension,
- the screw must be tighten strong by min. 9Newton m.

These 2 phases must be checked direct after the assembly of the five foot rack and regularly during the running time.



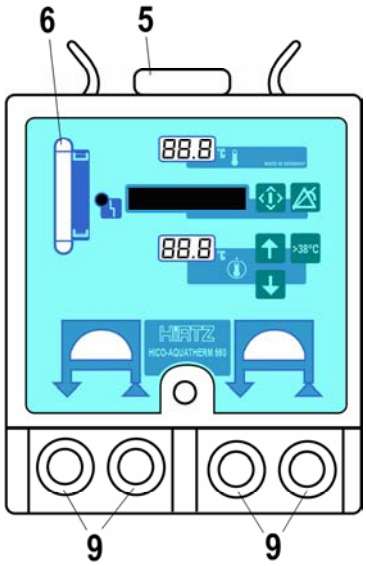
4.3 Connecting the HICO-AQUATHERM 660

⚠WARNING

Danger caused by water in connection with electricity.

► Only connect the unit to the mains supply after it has been filled.

4.3.1 Filling the system with water



- Unscrew the cap from the water filling socket (5), e.g. with a coin. Take care not to lose the sealing ring of the cap.
- Watch the water level indicator while filling (6). After filling the water level should be slightly below the MAX-mark.
- Fill the unit tank with distilled water[4], to which a germicidal agent[5] has been added.
- After filling turn the screw cap hand-tight back onto the water filling socket, until it is properly sealed.

NOTE

For initial filling of the unit please follow the procedure described in chapter 6.2.1.

⚠WARNING

Danger caused by water in connection with electricity.

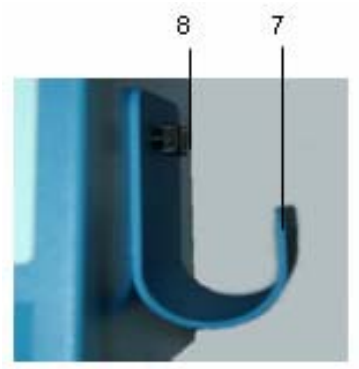
Water is electrically conductive.

► If water has been spilled when filling the unit, the unit must first be thoroughly dried and should only be connected to the mains supply and switched on after it has completely dried.

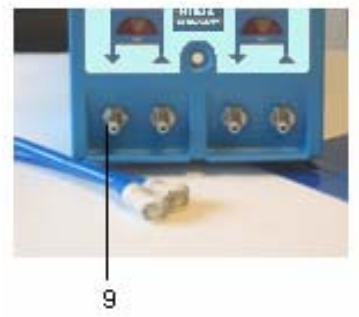
[4] The use of tap water is also possible, depending on the water quality (e.g. water hardness) the lifetime of water contacting components in the unit will be reduced!

[5] approx. 10 % SANOSIL-mixture (from Sanosil, Farchant) ⇨ (1l water + 100ml Sanosil-solution). The usage of a non-proportional share of disinfectants can reduce the lifetime of those parts of the unit who will come in touch with water!

4.3.2 Connecting the water mats



- The hose bracket (7) supplied with the unit eases the routing of hoses between mat and unit. To attach the bracket loosen two knurled screws (8) on the right hand side of the unit and use these to fasten the bracket.



- Push the hose couplings onto the couplings (9) on the unit. The couplings are plugged on correctly when the lock on the hose coupling engages in the coupling of the unit, so that the connection cannot come loose by itself.
- You can release the coupling again by pressing the small metal plate on the hose coupling and pulling off the hose.

NOTE

► The hoses of the water mat can not be "mixed up by mistake" when plugging on the couplings of the unit, because it does not matter which way the water flows through the water mat.

► Water mats can also be decoupled while the unit is switched on. Water dripping out of the coupling is in this case quite normal and does not indicate a leakage or defect.
In heating operation: Reduce the nominal temperature before you disconnect the water mat. Otherwise the water in the circuit of the unit will temporarily heat up above nominal temperature and possibly trigger the alarm TEMP.DIFF > 1 °C (depending on the time behaviour).

4.3.3 Electrical connection

⚠CAUTION

Danger caused by electric current

Defective cables and/or plugs can cause life threatening electric shock!

► Check the condition of unit cable and plug before connecting!

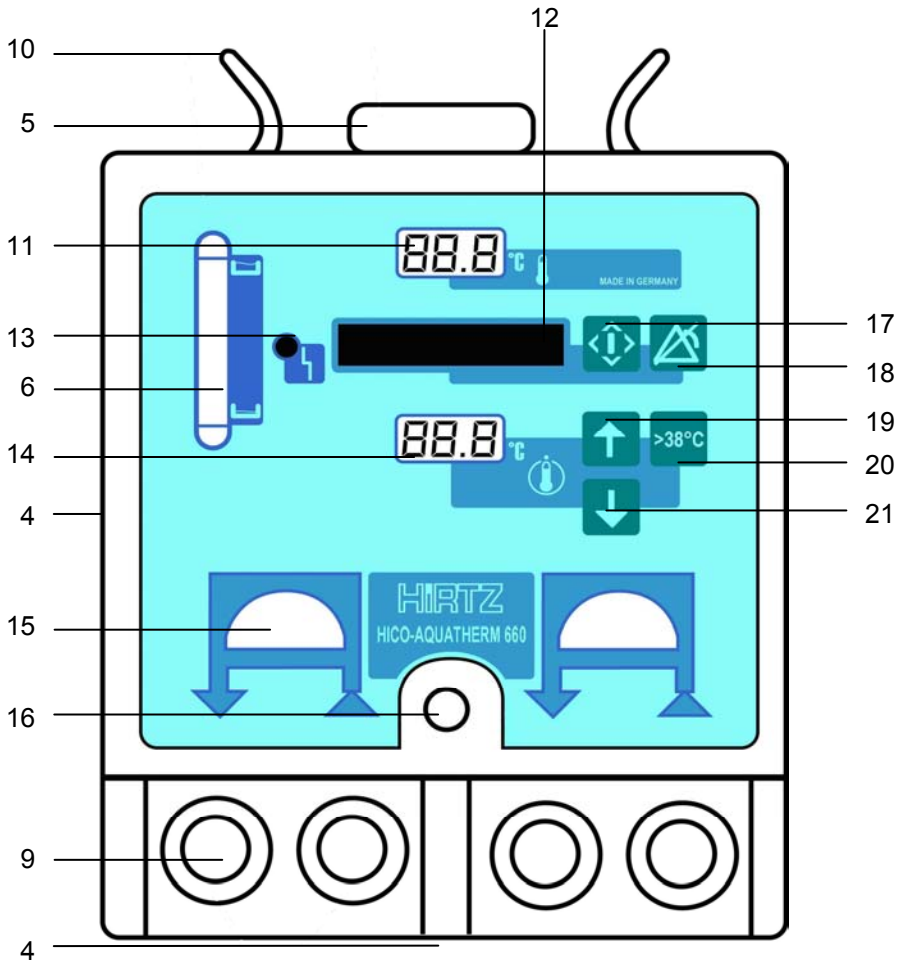
Please observe the following notes when connecting the unit electrically to ensure safe and fault free operation:

- Before connecting the unit compare the electric data (voltage and frequency) on the type plate with the data of your mains supply. These data must match to prevent the unit from being damaged.
  Please ask your electrics expert for advice, if in doubt.
- The electric socket must be protected by a 16 A circuit breaker.
- Use the cable supplied with the unit to connect the unit to the mains supply. The unit socket is on the back side of the unit (see page 22, views of unit).

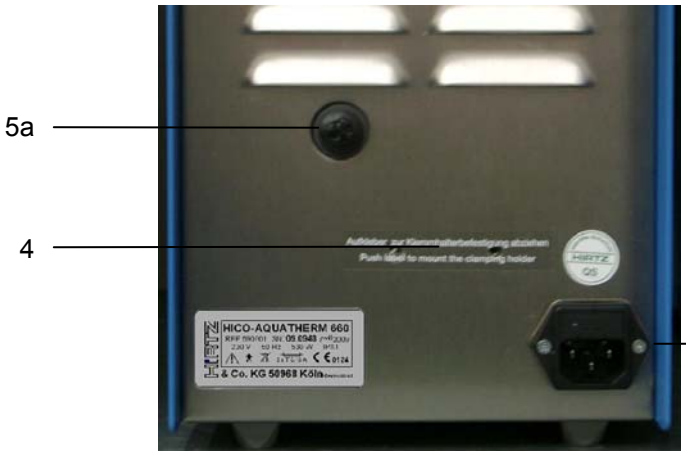
5 Function and design

This chapter contains important information about the design and function of the unit.

5.1 Views of the unit, control and display elements



4) Thread for clamping bracket (in side of housing, - bottom plate, -rear side)
5) Water filling socket with screw cap
6) Water level indicator
9) Hose couplings
10) Handles
11) Temperature display for water mat
12) Display for status and error messages
13) Fault lamp
14) Temperature display for nominal value
15) Water flow display
16) Mains switch
17) Function test
18) Alarm off
19) Nominal value higher
20) Release > 38 °C
21) Nominal value lower



Rear view (detail) of unit

5a) Water drain socket with screw cap

Miniature fuse and unit socket

5.2 Safety installations

5.2.1 Sensors

During operation the HICO-AQUATHERM 660 monitors

- the water level in the unit
- whether the water temperature in the circuit corresponds with the set nominal value
- whether mains voltage is applied
- whether the function is safe

and emits alarms in case of malfunction (see chapter 6.3).

5.3 Type plate

The type plate with the connection and performance data is located on the rear side of the unit:

5.4 Function

5.4.1 Basic principles

The hyperthermia unit HICO-AQUATHERM 660 serves the purpose of warming patients by means of water mats. The unit was developed under due consideration of the latest safety and application related knowledge about water mat systems.

The heat conductance between patient and water mat is solely achieved by surface contact. Thanks to its high heat capacity and heat conductivity water is an ideal transmission medium for this type of application.

The water is heated in a water tank inside the unit by means of heating elements and continuously pumped through the water mat by a centrifugal pump.

The HICO-AQUATHERM 660 is characterised by simple and safe use, reliability and compact design.

Its electronic control enables exactly controlled heat transmission to the patient while ensuring high operational reliability: The risk of local temperature accumulation is ruled out.

Operation of the HICO-AQUATHERM 660 is simple and intuitive, incorrect use is almost ruled out.

5.4.2 Indications / contraindications / side effects

The HICO-AQUATHERM 660 is used for

- Heat supply in case of intraoperative or postoperative hypothermia.
- Heat supply to stabilize the patient's temperature (normothermia).

Temperature transfer by means of water mats may be considered unsatisfactory if:

- the patient's body surface exceeds 0.5 m² (this corresponds with an approx. weight of 10 kg or an age higher than 14 months)
- less than 20 % of the water mat contacts the patient
- the contact pressure reduces the skin circulation. In this case there is an additional risk of bedsore.

Apart from this, the temperature on the patient should normally not exceed 41 °C, to prevent the risk of burning in case of long-term applications. With too high temperatures this risk is always apparent. At a water temperature of more than 41.5 °C the HICO-AQUATHERM 660 switches off electronically and mechanically to minimize this risk in case of an equipment fault.

In case of a heat loss and the related unintentional lowering of the patient's temperature (hypothermia) side effects may occur, as described below:

- autonomous reactions (among others shivering)
- electrolyte disturbances,
- higher diuresis,
- hyperglycaemia,
- high blood loss (among others due to reduced blood-clotting factors),
- increased rate of wound infection,
- risk of bedsore.

Side effects specifically related to water mat systems are not known.

6 Control and operation

This chapter contains important information for operation of the unit. Please follow these notes to avoid dangers and damages.

6.1 Before switching on

6.1.1 Inspections on the unit

Examine the unit for any external damage.

Check the water level before and after

- switching on the unit
- connecting the water mat.

The water level must be between the two marks on the water level indicator (6), preferably just below the maximum mark. The filling difference between both marks is approx. 1 litres.

Top up water, if

- the water level is below the minimum mark.
- you would like to connect an empty water mat and the water level is below the maximum mark.

6.1.2 Water mat

- Only connect original HICO water mats to the HICO-AQUATHERM 660.
- Check the water mats for external damage before connecting. Use only undamaged mats.
- Prepare a collecting basin in case a mat should start leaking.

Water mats can be connected and disconnected with the unit switched on or off.

NOTE

Disconnecting water mats with the unit switched on in heating operation: Reduce the nominal temperature before you disconnect the water mat. Otherwise the water in the circuit of the unit will temporarily heat up above nominal temperature and possibly trigger the alarm TEMP.DIFF > 1 °C (depending on the time behaviour).

6.1.3 Heat emission

Information: During operation the display shows the heat emitted (heat emission) by the unit to the heating mat, i.e. the heating power in Watt (W), which is emitted to the environment (air, contact area to the operating table, etc.) and to the patient.

The proportion of the indicated heat emission to the patient in percent depends on the type and size of the heating mat and is always lower than 100 %.

The better the heating mat (e.g. HICO-AQUASOFT) is thermally insulated towards the base (e.g. operating table) and the higher the proportion of the patient's contact area is to the total area of the heating mat, the higher the heat proportion for the patient.

6.2 Operation

6.2.1 Switching on for initial commissioning

- Switch on the unit with the push button (16); in switched-off condition the push button is flush with the front panel.
- Run the unit for about two minutes to remove any air from the circuit in the unit.
- Check the water level in the indicator (6); if necessary switch off the unit, disconnect it from the mains supply and fill up with water.
- Connect a water mat to the unit; mat and unit should be at the same level.
- Reconnect the unit to the mains supply, switch it on and run it for another two minutes to force all air out of the water mat.
- Check the water level in the indicator (6) again; if necessary switch off the unit, disconnect it from the mains supply and fill up with water.

6.2.2 Switching on in normal operation

- Switch on the unit with the push button (16); in switched-off condition the push button is flush with the front panel.
- Check the water level in the water level indicator (6), especially if you connected an empty water mat.

6.2.3 Function test

After switching on the device performs a function test. During this test watch whether all indicating elements behave as described below:

- a short audible alarm indicates that the unit is prepared for a possible power failure alarm

The unit now checks its self-sufficient protection and

- shows the result in the display (12)
- the temperature displays (11) and (14) show 88.8
- the fault lamp (13) lights up
- the audible alarm is on.

This test take a few seconds.

CAUTION

If the function tests were not completed successfully, the unit is no longer safe to operate.

Do not operate the unit if

► the unit does not emit the short signal for power failure alarm after switching on.

► the automatic function test of the unit automatically switches off the unit, because a defect in the independent protection was found.

► one or several displays are defective.

In cases like these have the unit checked by the HICO Customer Service.

6.2.4 Setting the temperature

- Set the nominal value for the water temperature - i.e. the temperature on the contact area between water mat and patient - with the two arrow keys (19) and (21). The temperature can be set in steps of 0.1 °C from 35 to 39 °C. The temperature display (14) shows the set nominal value.

- For nominal temperature values above 38 °C press the arrow key (19) and the release key (20) at the same time.

⚠WARNING

► At temperatures below 35 °C the patient increasingly loses heat.

► Temperatures above 38 °C supply the patient with heat at a higher rate.

► Places of the body, which are subjected to increased pressure, may suffer under pressure necrosis and/or burns, even at temperatures below 41 °C. This applies for long-term applications and risk patients[6] in particular.

NOTE

The temperature that can be controlled by the unit depends on type and size of the water mat.

NOTE

The unit does not regulate the temperature actively to a nominal temperature value that is lower than the actual temperature. The water mat is passively cooled by ambient temperature or by the body temperature of the patient. The display shows the message "TEMP.DIFF. > 1 °C", "ACTIVE COOLING", "NOT POSSIBLE".

[6] see Scott S.M., Thermal blankets injury in the operating room, Arch. Surg. 34, page 181, 1967

The heat transfer (heat supply) between patient and water mat will only take place if the temperature of the water mat is higher than the skin temperature of the patient at the contact area.

The measure of heat transfer is directly proportionate

- to the temperature difference between skin temperature and water mat temperature
- to the size of the contact area.

Intermediate layers impair the heat transfer (e.g. surgical cloths or gel mats).

Example for temperature difference:

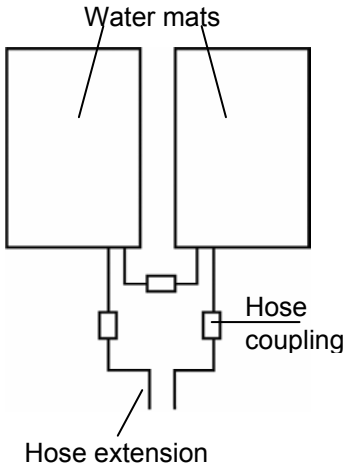
The heat transfer from mat to patient doubles when the temperature difference between water mat and patient is doubled. If the patient's skin has a temperature of 34 °C at the contact area and the water mat temperature is raised from 36 °C to 38 °C, the heat transfer will double, because the temperature difference has doubled from 2 °C to 4 °C.

Due to the thermal regulation of the patient this is only approximately true.

Example for enlarging the contact area:

In order to enlarge the contact area one can connect two water mats of the same or of different types (e.g. HICO-AQUASOFT+HICO-PU mats) in parallel and place these over or under the patient; (series connection of max. 2x2 SMALL mats or collars is possible; see schematic below in illustration 1x2).

With a bigger contact area the increased heat transfer is also achieved with a lower temperature difference. The mat temperature - i.e. the nominal temperature value - can thus be closer to the patient's temperature.



NOTE

When connecting too large or too many water mats a nominal value of 39 °C may probably not be reached. In this case set a lower nominal value.

Check the water flow in the display (15)!

6.2.5 Temperature control operation

⚠WARNING

There is a risk that the patient may be overheated or unintentionally undercooled.

► Monitor the patient's temperature when using the unit and the water mat on the patient.

If the nominal temperature value is set between 35 °C and 38 °C, the unit will start normal operation after switching on and the function test, and regulate the water temperature in the circuit to the set value.

If the set nominal value is higher than 38 °C, the unit will emit an audible alarm and the message "NOMINAL VALUE >38°C!", "RELEASE KEY" will appear in the display (12).

Check whether the nominal value is correct before pressing the release key (20).

The unit starts temperature control operation and the display (12) shows "HEATING ACTIVE", if the nominal temperature value is higher than the actual temperature value.

The unit does not regulate the temperature actively to a nominal temperature value that is lower than the actual temperature.

CAUTION

Only leave the water mat in contact with the patient in normal operation.

Due to the excellent heat conductivity of water the patient may cool down when the unit is switched off or the water mat is disconnected from the unit.

6.2.6 Note on handling water mats

NOTE

- ► When disconnecting water mats from the switched off unit, the mat should be lower than the unit. This prevents backflow and the mats stay sufficiently filled with water for the next use.
- ► Water mats connected to the unit should never be stored at a higher level than the unit, e.g. not on top of the unit. The water will in such cases flow from the mat back into the unit and flow over.

6.2.7 Obligations during operation

Check the water flow

During operation check the water flow through unit and mat at regular intervals. The sight glass of the water flow indicator (15) features an impeller wheel. With optimal water flow the individual blades of the impeller are not visible.

Carry out function test

During long-term operation check the independent protection manually at least once every day. For this purpose press the function test key (17) during operation. The unit now tests the safety electronics:

- the alarm sounds
- the temperature indicators show 88.8
- the red fault lamp (13) lights up
- the display shows FUNCTION TEST.

After successful testing the display shows the message FUNCTION TEST OK, the unit will automatically resume normal operation.

CAUTION

If the function test was not completed successfully, the unit is no longer safe to operate. In this case

► do not longer use the unit on a patient.

► have the unit inspected by the Customer Service.

6.2.8 Operator language

The status and error messages in the display (12) can be displayed in the languages: German, English, French, Spanish, Italian.

Set the display language as follows:

- Switching the device on

- Hold the key "Alarm off" (18) depressed for about 4 sec.; the language set last appears in the display.

- Keep pressing the arrow key "Nominal value higher" (19), until the desired language appears in the display.
- About 10 sec. after the last input the unit will return to its previous operating status, the language displayed last is active.

6.3 Alarms

6.3.1 General

The unit always emits visual and audible alarms. The operator is instantaneously informed about any malfunction, which in turn enhances the operational reliability of the system. The display (12) shows the fault condition, that has caused the alarm (except power failure alarm).

In case of alarms with low priority (see below) pressing the key "Alarm off" (18) will stop the audible alarm for 10 minutes. The error message in the display (12) is erased, the fault lamp (13) stays on as long as the alarm condition is present.

In case of alarms with high priority (chapter 6.3.3) the unit switches off all functions. The audible alarm cannot be interrupted. Switch off the unit by the mains switch (16), take it out of service and, if necessary, have it inspected by a Service Engineer (Customer Service / Medical Engineering).

6.3.2 Alarms with low priority

TEMP.DIFF > 1 °C

Should the water mat temperature deviate from the set nominal temperature by more than 1 °C during operation, the unit will trigger this alarm. The display shows "TEMP.DIFF. > 1 °C", the red fault lamp (13) lights and a signal sounds.

- Press the "Alarm off" key (18) to interrupt the audible alarm for 10 minutes.

NOTE

- ► Connecting or disconnecting a water mat during operation can cause an alarm triggering temperature difference.
- ► The alarm can be triggered in heating operation at low room temperatures and/or when connecting two or several water mats, because the specified nominal value (e.g. 39 °C) can in this case not be achieved. Reduce the number (size) of mats, until the unit is able to control the temperature reliably (!-Patient temperature-!).
- ► After switching on the unit and after changing the nominal temperature this alarm function is suppressed over a specified period of time.

WATER LEVEL!?

The unit triggers this alarm if the water level drops below the MIN-mark in the water level indicator (6) during operation. The display shows "WATER LEVEL!?", the red fault lamp (13) lights and a signal sounds.

- Press the "Alarm off" key (18) to interrupt the audible alarm for 10 minutes.
- Immediately fill up water, until the water level is just below the MAX-mark (6) (see chapter "Filling the system with water").

If no water is added, the alarm "LACK OF WATER!?", an alarm with high priority (see below) will be triggered.

CAUTION

- ► In case of a too low water level a sufficient water circulation can no longer be assured.
- ► A too low water level can cause damage to components of the unit and thus total failure of the unit.

6.3.3 Alarms with high priority

LACK OF WATER!?

The unit triggers this alarm if the operational reliability is endangered because of a too low water level. The display shows "LACK OF WATER!?", the red fault lamp (13) lights and a signal sounds, the unit switches heating and pump off.

The audible alarm cannot be interrupted with the "Alarm off" key (18).

a) Switch off the unit with the mains switch (16).

b) Leave the unit switched off for 30 minutes.

c) Fill up water, until the water level is just below the MAX-mark (6) (see chapter "Filling the system with water").

d) Switch the unit back on.

CAUTION

Strictly comply with the sequence described above. The unit may otherwise be damaged.

If the unit still emits an alarm take it out of service and have it inspected by a Service Engineer (Customer Service / Medical Engineering).

ALARM TEST DEFECT→CUSTOMER SERVICE

The unit triggers this alarm if it has detected a fault during the automatic or manual function test or has found that the independent protection does not respond. The display shows "ALARM TEST DEFECT" and "→CUSTOMER SERVICE", the red fault lamp (13) lights and a signal sounds.

The audible alarm cannot be interrupted with the "Alarm off" key (18).

- Switch off the unit with the mains switch (16).
- Leave the unit switched off for approx. 2 hours.
- Switch the unit back on.

If the unit still emits an alarm take it out of service and have it inspected by a Service Engineer (Customer Service / Medical Engineering).

UNDERTEMPERATURE CHECK UNIT

The unit triggers this alarm if the water tank temperature falls short of the measuring range (approx. 9 °C). The display shows "UNDERTEMPERATURE" and "CHECK UNIT". The red fault lamp (13) lights and a signal sounds. The temperature indicator shows - - . -.

The audible alarm cannot be interrupted with the "Alarm off" key (18).

- Switch off the unit with the mains switch (16).
- Take the unit to a warmer environment and wait for about 2 hours.
- Switch the unit back on.

CAUTION

► Store the unit only in the permissible temperature range, the unit may otherwise be damaged (10 - 40 °C).

► Operate the unit only in the permissible temperature range, the unit may otherwise not operate reliably and may be damaged (10 - 30 °C).

If the unit still emits an alarm take it out of service and have it inspected by a Service Engineer (Customer Service / Medical Engineering).

CHECK UNIT→CUSTOMER SERVICE

The unit triggers this alarm in case of various defects. The display shows "CHECK UNIT" and "→CUSTOMER SERVICE", the red fault lamp (13) lights and a signal sounds.

The audible alarm cannot be interrupted with the "Alarm off" key (18).

- Switch off the unit with the mains switch (16).

Take the unit out of service and have it inspected by a Service Engineer (Customer Service / Medical Engineering).

6.3.4 Power failure alarm

The unit triggers this alarm if the power supply fails during operation. The red fault lamp (13) lights and a signal sounds. All other displays are without function. The power accumulator in the unit receives the alarm for at least 10 minute without mains supply.

The audible alarm cannot be interrupted with the "Alarm off" key (18).

- Switch off the unit with the mains switch (16).

NOTE

The alarm automatically goes out when the power supply returns.

7 Cleaning and disinfection

This chapter contains important information about the cleaning and disinfection of the unit. Please follow these instructions to avoid damage caused by incorrect cleaning of the unit and to assure trouble-free operation.

7.1 Safety Advice

⚠CAUTION

Observe the following safety notes before starting to clean the unit.

- ► Pull out the mains plug before starting cleaning and disinfecting the unit.
- ► Prevent fluids from entering into the unit.
- ► Let the unit dry completely before switching it on again.

CAUTION

Sensitive surfaces.

The surfaces of unit and mats can be destroyed by using wrong cleaning agents and disinfectants.

- ► Use only disinfectants based on aldehydes, ammonium components or alcohols, which will not affect ABS-plastics as well as PVC and PU for all surfaces and parts.
- ► If possible do not use any phenol derivative based disinfectants, because these will shorten the lifetime of plastic materials.

7.2 Equipment

7.2.1 Finish

If possible use decalcified water. Only wipe the unit with a damp cloth. For cleaning use only warm water (max. 50 °C) with a mild commercial dish washer liquid. Wipe off again with clear water and wipe the unit dry with a cloth.

To disinfect the surface of the unit we recommend a wiping or area disinfection acc. to RKI- or DGHM-list[7] (e.g. Mikrozid from S&M or Sanosil from Sanosil). When using a disinfectant follow the instructions of the manufacturer.

Only switch on the unit after the disinfectant has evaporated completely.

7.2.2 Ventilation slots

Check the ventilation slots on the rear side of the unit regularly for dirt, but at the latest after 6 months. Remove external dirt, as far as this is possible. Dust deposits inside the unit will reduce the performance of the system. Have the dirt inside the unit cleaned out by a Service Engineer (Customer Service, Medical Engineering). Do not open the unit yourself.

[7] **R**obert-**K**och-**I**nstitut; **D**eutsche **G**esellschaft für **H**ygiene und **M**ikrobiologie
Lists available from mhp-Verlag, Wiesbaden

7.3 Water mats

If possible use decalcified water. Only wipe the mat with a damp cloth. For cleaning use only warm water (max. 50 °C) with a mild commercial dish washer liquid. Wipe off again with clear water and wipe the mat dry with a cloth.

To disinfect the surface of the unit we recommend a area, wiping or spraying disinfection acc. to RKI- or DGHM-list[7] (e.g. Mikrozid from S&M or Sanosil from Sanosil). When using a disinfectant follow the instructions of the manufacturer.

Only use the mat again after the disinfectant has evaporated completely.

Check the mat for damage, deformation or cracks; if necessary replace the mat.

8 Maintenance and safety related inspection

This chapter contains important information for maintenance of the unit. Please follow these instructions to avoid damage caused by inadequate maintenance of the unit and to assure trouble-free operation.

8.1 Maintenance

We recommend the conclusion of a maintenance contract with HIRTZ & Co. KG. By concluding a maintenance contract you fulfil the requirements

- of the BetrSichV BGV A2 (VBG 4) new BGV A3,
- the Medical Product Directive 93/42/EEC,
- the MPBetreibV,

all of which request regular technical inspection of the units

Furthermore, maintenance by our experts ensures maximum operational reliability and longevity of the unit.

CAUTION

Do not apply any other cleaning and decontamination methods than the ones recommended by HIRTZ & Co. KG.

Before introducing new methods check these together with HIRTZ & Co. KG.

Only this makes sure that the unit will not be damaged by this method.

8.1.1 Equipment

- Check the ventilation slots on underside and rear side of the unit for dirt, at the latest after 6 months. Dust deposits inside the unit will reduce the performance of the system. Have the dirt inside the unit cleaned out by a Service Engineer (Customer Service, Medical Engineering). Do not open the unit yourself.
- Make sure that the Customer Service or the Medical Engineer complies with the maintenance and safety related inspection intervals.

8.1.2 Water tank

Replace the water in the water tank at least every 6 months as follows:

- Disconnect the unit from the mains supply.
- Place a container (bucket, bowl, etc.) underneath or stand the unit on a water discharge facility (e.g. a sink).
- Unscrew the cap from the water filling socket (5), e.g. with a coin (do not lose the sealing ring for the cap).
- Unscrew the cap from the drain socket (5a), e.g. with a coin (do not lose the sealing ring for the cap).
- Tilt the unit backwards and let the water run out through the drain socket.
- Close the drain socket again.
- Fill the unit with water again, as described in chapter 4.3.1. The max. filling quantity of the tank is approx. 1,4 litre.

8.1.3 Hose couplings

The seal rings (O-rings) on all couplings are subject of aging and become dry and brittle. You should therefore cover the rings with a thin film of silicone paste or Vaseline every 6 months.

8.2 Safety related inspection

In order to maintain legal conformity and operational reliability as per Medical Product Directive 93/42/EEC (appendix I, point13.6.d) and MPBetreibV (§ 6(1)) the unit needs to be subjected to a safety related inspection every 12 months. The operator is solely responsible for the performance of this safety related inspection. Based on the MPBetreibV (§ 6 (4) 1.+3.) this safety related inspection must only be performed by HIRTZ & Co. KG or a qualified person. The safety related inspection covers at least the following points:

- Inspection of the device and application components for external damage, wear, aging and legibility of displays and inscriptions
- Measurement of the PE-resistance and the earth leakage current acc. to the testing facility and manufacturer's data
- Inspection of all functions by following the operating instructions
- Inspection of all safety functions acc. to manufacturer's data
- Inspection of all sensors acc. to manufacturer's data (for this purpose HIRTZ & Co. KG provides a Service Manual for authorized persons).

In order to maintain conformity with statutory safety regulations we recommend to conclude a Safety Related Inspection Contract with HIRTZ & Co. KG. We will in this case carry out the annual safety related inspections.

NOTE

For heavily soiled units or accessories returned to us for maintenance or repair, with which there is a suspicion of contamination by contact, we reserve the right to reject such units or components for safety reasons, or, after consultation, to subject these to additional treatment before performing a technical revision or damage analysis. Any additional costs arising from this must be borne by the customer.

Questions concerning service, maintenance or safety related inspection should be directly addressed to:

HIRTZ & Co. KG
Bonner Str. 180
D-50968 Cologne
Phone: +49 (0)2 21 / 3 76 78-0
Fax: +49 (0)2 21 / 3 76 78-85
E-mail: hirtz@hico.de

9 Trouble shooting

This chapter contains important information for fault localisation and trouble shooting. Please follow these notes to avoid dangers and damages.

9.1 Safety Advice

⚠CAUTION

- ► Repairs on electric devices must only be carried out by skilled professionals, which may have been trained by the manufacturer.
- ► Inappropriate repairs can cause considerable dangers for the user and damage to the unit.

NOTE

Opening of the unit by unauthorized persons will lead to the loss of any warranty claims.

9.2 Fault causes and rectification

Fault	Possible causes	Possible action
No or insufficient water circulation	1. Hoses or mat buckled 2. Couplings not locked properly 3. Unit positioned too far below the water mat 4. Excessive formation of foam 5. High weight of patient 6. Pump worn/defective	1. ensure correct routing or positioning 2. Couplings too tightly plugged together 3. Position unit at same height or above 4. Replace water* 5. Position the unit above the water mat 6. Customer Service*
Couplings are stiff	1. Seal rings dry and brittle	1. Grease seal ring with Vaseline, silicone grease or similar
Coupling connection permanently leaking	1. Outer, visible seal ring damaged or missing	1. Replace the seal ring*
Coupling valve of unconnected coupling permanently leaking	1. Inner seal ring damaged 2. Inner seal ring dirty	1. Customer Service* 2. Plug and release the coupling several times, if necessary Customer Service
Heat emission value not indicated. Display message: "HEAT EMISSION 0 W" or " HEAT-UP PHASE "	1. Temperature difference (nominal/actual)	1. Heat is only emitted at equal temperature
Alarm + display message: "ALARM TEST DEFECT" "->CUSTOMER SERVICE"	1. independent protection defective 2. Pump electrically defect	1. Customer Service* 2. Customer Service*
Alarm + display message one-time: "TEMP.DIFF > 1 °C"	1. Connect or disconnect water mat during operation	1. Reset alarm with "Alarm off" key
Alarm + display message every 10 minutes: "TEMP.DIFF > 1 °C"	1. Heating cartridge or pump defective 2. Excessive formation of foam in tank 3. Bypass interrupted 4. Insufficient heat emission	1. Customer Service* 2. Replace water* 3. Customer Service* 4. Do not operate unit continually (> 1 h) without heating mat*

Fault	Possible causes	Possible action
Alarm + display message: !WATER LEVEL!?" Can be reset with "Alarm off" key for 10 minutes	1. Water level too low 2. Unit not in horizontal position 3. Sensor deviation	1. Fill up water 2. Place the unit horizontally 3. Customer Service*
Alarm + display message: "LACK OF WATER!?" **Cannot** be reset with the !Alarm off" key	1. Water tank empty 2. Insufficient heat emission 3. Ambient temperature too high 4. Shorting sensor T2	1. Fill up water* 2. Do not operate unit continually (> 1 h) without heating mat* 3. Allow to cool down and observe max. ambient temperature* 4. Customer Service*
Alarm + display message: "CHECK UNIT" "->CUSTOMER SERVICE"	1. Various defects 2. Water tank empty 3. Sensor breakage/short circuit T1	1. Customer Service* 2. Fill up water* 3. Customer Service*
Alarm + display message: "CHECK UNIT" "UNDERTEMPERATURE"	1. Unit too cold (≤ 9 °C) 2. Sensor breakage T2	1. Warm up the unit for some time at room temperature* 2. Customer Service*
Unit completely without function and audible alarm	1. Mains failure 2. Mains plug has no contact 3. Fuse defective 4. Unit defective	1. Switch off the unit, until the mains supply is up again 2. Check plug on unit and mains socket for correct fit 3. Customer Service* 4. Customer Service*

* Switch off the unit immediately

10 Waste disposal of old unit

Old electric and electronic devices very often contain precious materials. However, they also contain harmful substances, which were necessary for their function and safety.

If disposed of as residual waste or handled incorrectly these can cause harm for human health and damage the environment. This device must **not** be disposed of with normal industrial or domestic waste!

NOTE

► According to the product reliability acc. to § 22 of the "Kreislaufwirtschafts- und Abfallgesetzes" (Recycling Economy and Waste Management Act) and the "Elektro- und Elektronikgesetzes" (Electrics and Electronics Act) § 2, section 1, cipher 8, the unit **must** be handed over to a corresponding communal collecting point or returned to the manufacturer

NOTE

► In accordance with waste management regulations of the user the water mat can be disposed off for incineration, together with domestic waste.

11 Warranty

The HICO-AQUATHERM 660 has been developed according to latest knowledge and is manufactured and tested by HIRTZ & Co. KG in strict compliance with highest technical standards.

However, should any defects occur during the period of 24 months starting with the date of purchasing by the end user, we guarantee free of charge replacement or free of charge repair of defects caused by material, design or production faults.

Under the following conditions, among others, warranty becomes null and void.

a) Damage caused by improper transport

b) Damage caused by environmental effects

c) Damage caused by improper handling

d) Use of impermissible accessories

e) Opening of unit by unauthorized persons

12 Technical data and accessories

12.1 Technical Data

HICO-AQUATHERM 660

Article-No. (REF):	590001
Rated voltage:	230 VAC 50 Hz
Power input:	530 W
Power consumption:	2.3 A
Nominal value range:	35 - 39 °C
Safety shut-down:	42.1 - 42.5 °C (independent safety shut-down). This results in a max. mat surface temperature of < 41 °C
Measuring range:	approx. 9 - 50 °C
Measuring deviation 1:	< +0.1 °C (display - water temperature)
Measuring deviation 2:	< +0.5 °C (display - contact surface temperature)
Correction value:	0.5 °C (water temp. - temp. display)
Sensor element:	2 x NTC 5K
Pump capacity	max. 19 l/min., max. 0.34 bar (10 W)
Heat output:	approx. 500 W max. (at 27 °C)
Warm-up time:	approx. 5 - 10 min. (20 - 37 °C)
Fuse value:	2 x T 3,15 L 250 V
Class/type of protection:	I, BF
Type of protection IP:	IP X1 (drip proof)
Risk class (93/42/EEC)	II b
Ambient temperature:	10 - 30 °C
Relative air humidity	approx. 30 - 70 %
Storage temperature:	10 - 40 °C
Air pressure	1013 hPa (+/-10 %)
Tank volume:	approx. 0.7/1.4 l (MIN/MAX)
permissible height difference	max. 1 m (unit/water mat)

Dimensions WxHxD:	approx. 200 x 290 x 330 mm
Weight:	approx. 9 kg(filled)
Noise emission:	approx. 35 dB(A) (1 m)
Alarm level:	> 65 dB(A) (3 m)
Test basis:	Medical Product Directive 93/42/EEC, IEC 601-1, IEC 601-1-2, IEC 601-2-35
UMDNS-Code:	17-648

The right for technical modifications remains reserved

The degree of electric protection in the application part corresponds with TYPE BF.

12.2 Accessories

Only original HICO water mats may be used in connection with the HICO-AQUATHERM 660 (necessary accessories). The required information about HICO water mats can be found in the corresponding brochures and price lists.

Hose extension, approx. 3 m (necessary accessories)

Five-castor stand incl. clamping bracket; height approx. 68 cm (optional equipment).

13 Guidelines and declaration of manufacturer

Guidelines and declaration of manufacturer – electromagnetic emissions

Tables for electric medical equipment General information: - reduced version
Table 201

Line			
1	Guidelines and declaration of manufacturer – electromagnetic emissions		
2	The unit or system is intended for operation in an environment as described in the tables and texts of these operating instructions. The customer or user of this unit or system should make sure that it is actually operated in this type of environment.		
3	Interference emission measurements	Conformance	
4	HF-emissions Acc. to CISPR 11	Group 1	
6	HF-emissions Acc. to CISPR 11	Class B	
7	Emissions of harmonics acc. to IEC 61000-3-2	Class A	
8	Emissions of voltage fluctuations/flickering acc. to IEC 61000-3-3	Not applicable.	
9		[see 6.8.3.201 a) 3) and picture 201]	

Table 202

Interference immunity tests	IEC 60601-test level	Conformity level	
Electric static discharge (ESD) acc. to IEC 61000-4-2	±6 kV contact discharge ±8 kV air gap discharge	±6 kV contact discharge ±8 kV air gap discharge	
Quick transient electric disturbances/busts Acc. to IEC 61000-4-4	±2 kV for mains lines ±1 kV for input and output lines	±2 kV for mains lines ±1 kV for input and output lines	
Surge voltages (surges) acc. to IEC 61000-4-5	±1 kV normal-mode voltage ±2 kV common-mode voltage	±1 kV normal mode voltage ±2 kV common mode voltage	
Voltage dips, short-term interruptions and fluctuations in the supply voltage acc. to IEC 61000-4-11	<5 % UT (> 95 % dip in UT) for ½ period 40 % U (60 % dip in UT) for 5 periods 70 % UT (60 % dip in UT) for 25 periods < 5 % UT (> 95 % dip in UT) for 5 s	< 5 % UT (> 95 % dip in UT) for ½ period 40 % U (60 % dip in UT) for 5 periods 70 % UT (60 % dip in UT) for 25 periods < 5 % UT (> 95 % dip in UT) for 5 s	
Magnetic field in supply frequency (50/60 Hz) acc. to IEC 61000-4-8	3 A/m	3 A/m	

Table 204: NON life-supporting systems

Interference immunity tests	IEC 60601-test level	Conformity level	
Conducted HF-disturbances acc. to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V	
Radiated HF-disturbances acc. to IEC 61000-4-3	3 V_{eff} 80 MHz to 2.5 GHz	3 V/m	
Radiated HF-disturbances acc. to EN 60601-2-35	10 V/m	10 V/m	

Table 206: Electrical clearance to wireless telecommunication facilities

	Electric clearance depending on transmission frequency m		
Nominal power of transmitter W	150 kHz to 80 MHz d=P*exp0.5*3.5/V1	80 MHz to 800 MHz d=P*exp0.5*3.5/E1	800 MHz to 2.5 GHz d=P*exp0.5*7/E1
0,01	0.12 m	0.12 m	0.24 m
0,1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.34 m
10	3.69 m	3.69 m	7.38 m
100	11.67 m	11.67 m	23.34 m

14 Brief instructions

- Connect the unit to the mains supply.
- Connect the water mat to the unit.
- Check the water level on the unit.
- Switch on the unit by the mains switch (0 / I) and watch the automatic function test.

- If the nominal temperature value is > 38 °C or < 35 °C when switching on, an alarm will be emitted. Acknowledge and start by pressing the release key.

- Set the temperature with the arrow keys.

- For temperatures higher than 38 °C press arrow key and release key together.
- Depending on the application place the water mat under or over the patient.
- Monitor the body temperature of the patient.
- Watch the water level and the water flow on the unit.

- In case of continuous operation perform a manual function test once every day by pressing the "Function test" key.

- Audible alarms of low priority can be interrupted with the "Alarm" key.
- Alarms with high priority cannot be interrupted. Switch off the unit with the mains switch (16).

NOTE

In case of an alarm with high priority the unit will switch off all functions. Take the unit out of service and submit it to a Service Engineer for inspection and to re-establish the operational reliability.

⚠WARNING

There is a risk that the patient may be overheated or undercooled.

► Monitor the patient's temperature when using the unit and the water mat on the patient.

⚠CAUTION

Do not start the unit if

► the display has failed,

► individual segments of the temperature display have failed (temperature can no longer be read reliably),

► the red fault lamp (13) lights permanently or not at all (function test),

► the signal sounds permanently or not at all (function test),

► the unit does not respond to key operation,

► the unit does not respond as described in the chapter 6.2.3 "Function test" when switching on or when running a function test.

Notes